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IP DEPARTMENT OF PIPER RUDNICK LLP  
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/481,990

Applicant(s)

LESAGE ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *1. Formal Matters*

- A. The Amendment, filed 11/26/03, has been entered into the record. Claims 11 and 12 were pending. Claim 12 has been cancelled. Claim 27 has been added. Therefore, claims 11 and 27 are pending and are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### *2. Double Patenting*

- A. Claim 11 remains rejected and new claim 27 is also provisionally rejected over Application Nos. 09/436,265; 09/939,483; 09/939,484; and 09/892,360 as being obvious over one or more claims of co-pending applications. Applicants request that further treatment of the rejection be held in abeyance.

### *3. Claim Rejections - 35 USC § 101*

- A. Claim 11 remains rejected and new claim 27 is also rejected under 35 USC 101 for the reasons already of record on page 4 of the Office Action dated 5/23/03. Applicants argue that the previous Office Action apparently applies Example 12 of the Utility Examination Guidelines as a model for the utility rejection. Applicants, however, respectfully submit that Example 12 is inapplicable to the current application. Rather, Applicants respectfully submit that the current application is more analogous to Example 10 of the Utility Guidelines. Applicants argue that they have disclosed a particular SEQ ID NO, which encodes a potassium channel protein. Similarly, Example 10 reveals a SEQ ID No. which encodes a DNA ligase. Applicants argue that there are over 80 potassium channels known in the art, which demonstrate a wide range of physiological roles within various organisms. Applicants also state that they had previously submitted the paper by Wildemann et al., to show that the Applicants' TWIK protein is operative in the nervous system pathology, and consequently, can be used for treatment and identification of associated nervous system disorders and that the identification of a TWIK deficiency, once identified, would be useful to observe a pathological effect exhibited by the resulting TWX deficiency. Applicants have clearly demonstrated the pharmacological action of two separate drugs on TWX channels. Learning how to control potassium channel currents in an organism provides an invaluable tool in both diagnostic and treatment of conditions associated with channel disorders and that the gene of the TWIK channel has been located on chromosome 1 at position q42-q43. Consequently, the chromosomal location of this gene

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can act as a determinant for the identification of genetic diseases associated with TWIK potassium channel proteins.

These arguments have been considered, but are not deemed persuasive. As stated by Applicants, Example 10 of the Utility Training Guidelines provides a specific example of a DNA ligase. Respectfully, this example is not analogous to the present example. DNA ligases are well-known in the art to have a very specific function in DNA replication. The artisan, given a DNA ligase, would know its exact utility. This is not the case with the potassium channel of the present invention. As Applicants have argued, there are over 80 known potassium channels known in the art which demonstrate a wide range of physiological roles within various organisms. Therefore, unlike the role of DNA ligases, which do not have a wide range of physiological roles, potassium channels would be much more difficult to characterize. In other words, the artisan would not know the specific and substantial utility of the potassium channel, other than to transport potassium. The specification does not teach what the difference is between the potassium channel of the present invention and the approximately 80 other potassium channels known in the art. The fact that Applicants' TWIK protein is operative in nervous system pathology, and consequently, can be used for treatment and identification of associated nervous system disorders and that the identification of a TWIK deficiency, once identified, would be useful to observe a pathological effect exhibited by the resulting TWX deficiency, is, respectfully, not persuasive. Numerous proteins are involved in nervous system pathology. This is not a specific nor substantial well-established utility of the protein of the present invention. The specification does not teach the artisan how this protein specifically functions in the nervous system, nor does it teach any nervous system disorders associated with the TWIK protein of the present invention. Similarly, all DNA maps to a specific location on a chromosome and this, again, in the absence of an associated disease state, is neither a specific nor substantial utility of the protein, or gene, of the present invention. It is believed that all pertinent arguments have been addressed.

#### ***4. Claim Rejections - 35 USC § 112, first paragraph - enablement***

A. Claim 11 remains rejected and new claim 27 is also rejected under 35 USC 112, first paragraph, for the reasons already of record on page 5 of the Office Action dated 5/23/03 as well as for the reasons given in the above rejection under 35 USC 101. Applicants have not addressed this argument. Regardless, the claims remain rejected for the reasons discussed above.

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B. Claim 11 remains rejected and new claim 27 is also rejected under 35 U.S.C. 112, first paragraph, for the reasons already of record on pages 5-6 of the Office Action dated 5/23/03. Applicants argue that they have amended claim 11 to further point out the specific structural and functional aspects of the TWIK family of proteins. In this respect, the Applicants have identified that TWIK comprises SEQ. ID. NO:2, and functionally equivalent derivatives, which have clearly distinguishable structural features which would allow one skilled in the art to identify those sequences which were functional equivalents to SEQ. ID. NO:2.

These arguments have been considered, but are not deemed persuasive. First, Applicants have not clearly differentiated their arguments under 35 USC 112, first paragraph, written description vs. scope of enablement. Regardless, though Applicants did add further limitations to claim 11, the scope of the claim is still excessive. Applicants have only identified one TWIK protein (SEQ ID NO:2). The specification still does not provide any guidance or working examples of any other TWIK proteins which have these functional limitations. Furthermore, it is not predictable to the artisan how to make any functional TWIK proteins other than SEQ ID NO:2. Applicants have provided a 'discussion' of various domains and regions which should be present in a TWIK protein, but Applicants have not identified which amino acids would be critical in maintaining the functional characteristics of a TWIK protein. In other words, neither the claims as written, nor the specification, teaches the artisan how to make, or identify, a functional TWIK protein, especially given the large number of potassium channel proteins known in the art, all which have uses.

Therefore, the breadth of the claim remains excessive with regard to claiming any TWIK-I protein, or functionally equivalent derivatives of SEQ ID NO:2, which meet the claimed limitations. There remains a lack of guidance and working examples of any TWIK protein other than SEQ ID NO:2. Furthermore, it is still not predictable as to what changes can be made to the protein of SEQ ID NO:2 and which would allow it to retain its potassium channel functions. Therefore, the Examiner maintains that undue experimentation would be required to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

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**5. Claim Rejections - 35 USC § 112, first paragraph – written description**

A. Claim 11 remains rejected and new claim 27 is also rejected under 35 U.S.C. 112, first paragraph, for the reasons already of record on page 7 of the Office Action dated 5/23/03. Applicants arguments are the same as seen in paragraph 4B above. Applicants have not clearly differentiated their arguments under 35 USC 112, first paragraph, written description vs. scope of enablement. Therefore, the above arguments are pertinent here.

Again, the specification provides a written description of only one TWIK protein (SEQ ID NO:2). No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical amino acid residues which would structurally characterize the genus of TWIK proteins claimed, including those from different species, which are further not described; thereby not meeting the written description requirement under 35 USC 112, first paragraph.

**6. Claim Rejections - 35 USC § 112, second paragraph**

A. The rejection of claims 11 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to further clarify the definition of "TWIK."

**7. Claim Rejections - 35 USC § 102**

A. The rejection of claim 11 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to further describe the characteristic of the TWIK protein of the invention, which are not taught by Ketchum et al.

**8. Conclusion**

A. No claim is allowable.

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***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
December 30, 2003



ROBERT LANDSMAN  
PATENT EXAMINER